APR 20 2012

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Safety Screw Connector is provided below.

Device Common Name: Gastrointestinal tubes and accessories

Device Proprietary Name: Safety Screw Connector

510(k)# K113719

Submitter:
Abbott Nutrition
Abbott Laboratories
3300 Stelzer Road
Columbus, OH 43219-3034

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Classification Regulation: 21 CFR 876.5980

Panel: Gastroenterology/Urology

Product Code: KNT

Indication for Use:
The sets are intended to deliver liquid nutrition formulas or water to an enteral access device (a feeding tube).

Device Description:
The subject of this 510(k) is a modified proximal connector for Abbott Nutrition enteral feeding sets. The proximal connector connects the tubing of the enteral feeding set to the source of the nutrition (i.e., the container of the enteral nutritional formula).

The modified design is the Safety Screw Connector and is compliant with the new AAMI/ISO Standard 80369-1 (*Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements*). This same design is being used for currently marketed competitive enteral nutrition sets.

This bundled 510(k) is a modification of the following three Class 2 nutrition devices:

- K943240 Flexiflo® Six Enteral Nutrition Pump Set: KNT, Class 2, 876.5980, Gastroenterology/Urology (currently marketed as the Patrol® Pump Set with Piercing Pin)
- K915735 Flexiflo® Quantum Enteral Pump Sets and Enteral Nutrition Containers: KNT, Class 2, 876.5980, Gastroenterology/Urology (currently marketed as two versions; Flexiflo® Quantum Pump Set with Piercing Pin and the Flexiflo® Quantum Pump Set with Piercing Pin and Flush Bag)
- PREAMENDMENT Gravity Feeding Sets: KNT, Class 2, 876.5980, Gastroenterology/Urology

Performance Data:
The following tests were conducted in support of the substantial equivalence:

- Mechanical test for verifying non-interconnectable characteristics of Safety Screw Connector and other connectors (ANSI/AAMI/ISO 80369-1:2010)
- Delivery accuracy and feeding system performance assessment testing of Safety Screw Connector
- Biocompatibility testing for the Safety Screw Connector and the RTH Adapter Cap
- Tensile strength testing for the bond junction between the Safety Screw Connector and tubing

Substantial Equivalence:
The Abbott Nutrition enteral feeding devices with the Safety Screw Connector are substantially equivalent to commercially marketed Abbott Nutrition sets in terms of principle of operation and intended use. The new design reduces the risk of unintentional misconnection to another type of

tube. The risk analysis showed that the new connector design does not raise new questions of safety and effectiveness. Performance testing showed that the new designs are equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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APR 2 0 2012

Re: K113719
Trade/Device Name: Safety Screw Connector
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 15, 2012
Received: March 16, 2012

Dear Dr. Zola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K113719

Device Name: Safety Screw Connector

Indications For Use:

The sets are intended to deliver liquid nutrition formulas or water to an enteral access device (a feeding tube).

Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113719